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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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ABBOTT LABORATORIES
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100 ABBOTT PARK ROAD
ABBOTT PARK IL 60064-6050

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EXAMINER

HARRIS, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/549,342

Applicant(s)
Colpitts And Russell

Examiner
Alana M. Harris, Ph. D.

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-78 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-78 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7 and 39-47, drawn to a purified multimeric polypeptide antigen (MPA), classified in class 424, subclass 184.1. Claims 39 and 40 will be examined with Group I to the extent the composition of matter consists solely of antigens.
 - II. Claims 8, 9, and 38, drawn to an antibody and a method of making said antibody, classified in class 530, subclass 387.1.
 - III. Claims 10-37 and 76, drawn to a method of detecting the presence of a MPA comprising contacting a test sample with an antibody, classified in class 435, subclass 7.1. Claim 76 will be examined with Group III to the extent that the method comprises antibodies.
 - IV. Claims 48-51, drawn to a method of detecting breast cancer, classified in class 424, subclass 179.1.
 - V. Claims 52-55, drawn to a method of treating breast cancer, classified in class 514, subclass 8.
 - VI. Claims 56-58, drawn to a method of diagnosing breast cancer, classified in class 435, subclass 40.52.
 - VII. Claims 59-62, drawn to a method of diagnosing breast cancer, classified in class 435, subclass 7.23.

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- VIII. Claims 63 and 64, drawn to a method of detecting breast cancer in a patient comprising , classified in class 436, subclass 536.
- IX. Claims 65-68, drawn to a method of enhancing recognition of MPA, classified in class 436, subclass 538.8.
- X. Claims 69 and 70, drawn to a diagnostic reagent, classified in class 435, subclass 41.
- XI. Claims 71 and 75, drawn to a method for detecting the presence of a MPA comprising contacting the sample with a labelled antigen, classified in class 435, subclass 7.1. Claim 75 will be examined with Group XI to the extent that the method comprises a labelled antigen.
- XII. Claim 72-75, drawn to a method for detecting the presence of a MPA comprising contacting sample with a labelled antibody, classified in class 435, subclass 7.1. Claim 75 will be examined with Group XII to the extent that the method comprises a labelled antibody.
- XIII. Claims 76-78, drawn to a method for detecting the presence of antibody specific for a MPA comprising contacting sample with an anti-antibody, classified in class 530, subclass 387.2.

- 2. The inventions are distinct, each from the other because of the following reasons:

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Groups I, II and X are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups III-IX and XI-XIII differ in the method objectives, method steps and parameters and in the reagents used.

Inventions of Group I and each of Groups III, IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can also be used in the methods of Groups III, IX and XI.

Inventions of Group II and each of Groups III-VI, IX and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group II can also be used in the methods of Groups III-VI, IX and XII.

Inventions of Group X and each of Groups III, IV, VI-VII and XI-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the

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following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group X can also be used in the methods of Groups III, IV, VI-VII and XII-XIV.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Cheryl Becker on March 29, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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6. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at Anthony.Caputa@uspto.gov or 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

7. Papers related to this application may be submitted to Group 1642 by facsimile transmission. Papers should be faxed to Group 1642 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Crystal Mall One Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)308-0196.


SHEELA HUFF
PRIMARY EXAMINER